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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,424	12/22/2000	Ram Pratap	K&S-0100-US	8031

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EXAMINER	
WARE, TODD	
ART UNIT	**PAPER NUMBER**
1615	7

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,424	PRATAP ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *13-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of declaration filed 5-22-01, election filed 4-12-02 and information disclosure statement filed 4-29-02 is acknowledged.

1. Applicant's election with traverse of Group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that examination of all the claims would not pose undue burden on the examiner since Groups I, III, and IV are classified in the same class. This is not found persuasive because classification in the same class is insufficient to demonstrate that search and examination would not impose undue burden upon the examiner. Indeed restriction is proper even when related inventions are classifiable together when each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors (MPEP 808.02). In the instant case, none of the subject matter for each of the Groups as indicated in the Restriction Requirement of 3-12-02 is required for the other groups and they have different modes of operation, different functions, and different effects.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 13-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Information Disclosure Statement

3. The information disclosure statement filed 4-29-02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of memory disorders, does not reasonably provide enablement for controlling or preventing cognitive dysfunction, hyperglycemia and some infective conditions of the skin in mammals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims, state of the art, guidance of the specification, predictability if the art, and the working examples. All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

Nature of the Invention: All rejected claims are drawn to the methods of controlling or preventing cognitive dysfunction, hyperglycemia and some infective conditions of the skin in subjects with the administration of the instant composition. The nature of the invention is extremely complex in that it encompasses anticipating multiple complex disorders having unrelated manifestations and subsequently administering the instant composition.

Breadth of Claims: The complex nature of the claims is exacerbated by the breadth of the claims. The claim encompasses prevention of complex disorders that may have potential causes other than those disclosed in the specification. This may or may not be addressed by the administration of the composition. Moreover, the specification is directed to cognitive disorders due to conditions relating to memory (i.e. Alzheimer's Disease and Korsakoff's Disease). However, numerous other cognitive disorders, such as schizophrenia, Down's Syndrome, or retardation are encompassed by the instant claims. "Cognitive dysfunction" would be any disorder relating to interference with one's awareness with perception, reasoning, judgment, intuition, and memory or the mental process by which knowledge is acquired.

State of the Art: The state of the art does not recognize the administration of compositions to prevent the disorders as required in the instant claims. The state of the art recognizes the treatment of the symptoms of these disorders but not their cure.

Guidance of the Specification: The guidance given by the specification on how to prevent the disorders is absent. Guidance for treatment of memory disorders,

hyperglycemia, and skin infections is provided, however, no evidence that these conditions are prevented is provided.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to completely controlling or preventing memory disorders, hyperglycemia, and skin infections in mammals with the administration of the instant composition makes practicing the claimed invention unpredictable in terms of the prevention of the disease.

The Amount of Experimentation Necessary: Although the art provides a certain level of guidance with regards to the use of dopamine agonists to predict treatment of sexual dysfunction, these teachings do not provide sufficient guidance where the specification is lacking. The art demonstrates treatment of memory disorders, hyperglycemia, or skin infections in mammals, but does not teach elimination (prevention) of these conditions. Therefore, the practitioner would turn to trial and error experimentation to make/use the instant compositions for preventing memory disorders, hyperglycemia, or skin infections in mammals, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

For examination purposes, the phrase "controlling or preventing" is interpreted as "treating" the instant conditions.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term " some " in claim 1 is a relative term which renders the claim indefinite. The term " some " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification provides support for fungal infections, however numerous other kinds of infections exist (i.e. bacterial and viral). Furthermore, treatments for one type of infection may not necessarily work for another type of infection. For example an antibacterial for gram positive bacteria would not be expected to treat a viral infection.

Recitation of "as applicable to the conditions" in claim 2 is indefinite. What determines applicability of the conditions and to whom are they applicable? Furthermore, clarification regarding the antecedent basis for "conditions" in claim 2 is requested, since this word has multiple meanings such as "a requirement, prerequisite, or qualification." For purposes of examination, antecedent basis for "conditions" is understood to stem from the dysfunctions of claim 1. Verification is requested.

Recitation of "other pharmaceutically acceptable additives" in claim 3 is indefinite since the claim includes elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claims unascertainable.

Recitation of "suitable" in claims 5 and 11 is indefinite. What determines whether the proportions are suitable and to whom are they suitable? What amount results in a proportion that is suitable?

9. Regarding claim 7, the phrase "like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by " like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

10. Recitation of "male swiss" in claim 8 is indefinite. As written, humans (specifically male, Swiss) are encompassed. However, the specification refers to male swiss mice and it appears "mice" was inadvertently omitted.

11. The wording of claim 8 is grammatically confusing. It appears, the method of administering the compositions is for reversal of atropine induced amnesia, however as written, the claim does not appear to provide steps for the phrase "wherein."

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4, 7-8, and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Thyrox T-3 (1996).

14. Thyrox T-3 discloses a tablet composition that treats neurological disorders, memory loss an depression comprising gum guggal extract.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-4, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thyrox T-3 (1996).

Thyrox T-3 teaches a tablet composition that treats neurological disorders, memory loss and depression comprising gum guggal extract. Thyrox T-3 does not teach the dosage of instant claim 9, however it would have been obvious to one skilled in the art at the time of the invention to adjust the dose to increase or decrease the amount of effect of the guggul extract.

18. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thyrox T-3 (1996) in view of Remington's (1995).

Thyrox T-3 teaches a tablet composition that treats neurological disorders, memory loss and depression comprising gum guggal extract. Thyrox T-3 does not teach the dosage of instant claim 9, however it would have been obvious to one skilled in the art at the time of the invention to adjust the dose to increase or decrease the amount of effect of the guggul extract. Thyrox T-3 also does not teach inclusion of both starch and microcrystalline cellulose in the formulation.

Remington's teaches that both starch and microcrystalline cellulose are common ingredients in tablet formulations as diluents, binders and disintegrants.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine these references and include starch and microcrystalline cellulose in the tablet formulations of Thyrox T-3 to add bulk, impart cohesiveness to the tablets and facilitate breakup after administration.

19. Claims 1-3, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thyrox T-3 (1996) in view of Reisberg et al (4,385,053; hereafter '053).

Bink (6,113,949)

'949 teaches weight control tablet compositions comprising guggul extract and phosphatidylcholine. '949 does not teach treating cognitive memory dysfunctions with the taught compositions.

'053 teaches treatment of memory impairment with phosphatidylcholine.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to use the compositions of '949 for treatment of memory impairments. Furthermore, it is submitted that it would have been obvious to one skilled in the art at the time of the invention to adjust the dose to increase or decrease the amount of effect of the guggul extract.

20. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink (6,113,949; hereafter '949) in combination with Reisberg et al (4,385,053; hereafter '053) and further in combination with Remington's (1995).

'949 and '053 are both relied upon for all that they teach as stated previously. Neither reference teaches inclusion of starch or microcrystalline cellulose.

Remington's teaches that both starch and microcrystalline cellulose are common ingredients in tablet formulations as diluents, binders and disintegrants.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine these references and include starch and microcrystalline cellulose in the tablet formulations of '949 to add bulk, impart cohesiveness to the tablets and facilitate breakup after administration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
May 4, 2002

THURMAN K. PAGE
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